

## **REMARKS**

### **Claim Rejections – 35 USC §103**

Claims 1-21, 28-31 and 33-60 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuslich, and claims 22-27 have been rejected as being unpatentable over Kuslich in view of U.S. Patent No. 6,371,989 to Chauvin.

As an initial matter, the Applicant notes that dependent claim 33 has been rewritten in independent form, and that independent claims 30 and 31 have been cancelled from the subject application without prejudice for possible submission and consideration in a continuing application.

Additionally, independent claims 1, 33, 37 and 45 have been amended to recite that the expansion member is engaged with the first and second axial walls at a location intermediate the end portions/end walls of the implant “and extending transversely between and engaging central portions of said first and second axial walls” to provide expansion/outward deformation along the transverse axis. Independent claim 50 has been similarly amended to recite that the intervertebral implant is expanded by engaging the expansion member with the first and second axial walls at a location intermediate the first and second transverse end walls, with the expansion member “extending transversely between and engaging mid-portions of the first and second axial walls” to engage the first and second axial walls against vertebral bodies.

The amendments incorporated into independent claims 1, 33, 37, 45 and 50 regarding the expansion member extending transversely between “and engaging” central portions/mid-portions of the axial walls should already be apparent from the previously-presented claim language (i.e., the expansion member is “engaged with said first and second axial walls” at a location intermediate the end portions/walls and “extending transversely between” the central portions/mid-portions of the axial walls). The additional recitation regarding the expansion member extending transversely between “and engaging” central portions/mid-portions of the axial walls has been added to the independent claims to further focus on the distinguishing aspects of the claimed invention over Kuslich. However, the Applicant submits that no new issues are presented by the amendments to independent claims 1, 33, 37, 45 and 50 that would require further consideration and/or searching.

The primary basis for the rejection of the pending independent claims as being obvious over Kuslich is set forth in the Office Action via the following assertion:

Although Kuslich may not explicitly or unambiguously show that the expansion member is or may be at the claimed location, it is noted that it would have been obvious . . . to have located the expansion member intermediate pairs of opposite end portions and extending transversely between central portions of axial walls, for example, *since it would have been held that mere relocation of parts of an invention involves only routine skill in the art*". (Pgs. 2 and 3; emphasis added).

The Applicant notes that the cited passage presents the sole basis in support of the assertion that engagement of the expansion member with the first and second axial walls of the implant body at an intermediate/central location would have been obvious in view of Kuslich. As will be more fully addressed below, the Applicant submits that the abbreviated rationale set forth in the Office Action regarding the rejection of the pending independent claims as being obvious over Kuslich is conclusory, and does not present a *prima facie* case of obviousness.

As illustrated in Figures 1-3 of Kuslich, the implant 10 includes an implant body 12 and an implant expander 14. The implant body 12 is comprised of a tubular shell 22 having a several axially-extending ribs 26 that are interconnected via a pair of end rings 23. The implant expander 14 includes a tie rod 16 and an attachable end cap 18. As shown in Figure 4, the tie rod 16 includes an integrally molded end cap 32 and a tie rod post 40 that is provided with a plurality of barbs 44. As shown in Figures 6 and 7, the attachable end cap 18 includes a notched bore 52 having notches 54 that are complementarily sized to receive the barbs 44 of the tie rod 16. The end caps 18, 32 of the implant expander 14 abut the end rings 23 of the implant body 12. As the tie rod 16 is pulled through the notched bore 52 in the end cap 18, the end caps 18, 32 are drawn together, thereby exerting a compressive force onto the end rings 23 of the implant body 12, which in turn causes the axially-extending ribs 26 to arc outwardly to transition the implant body 12 to the spherical configuration illustrated in Figures 1 and 2.

The Applicant submits that the implant expander 14 of Kuslich does not engage central portions of the axially-extending ribs 26, but instead includes end caps 18, 32 that engage the end rings 23 of the implant body 12, and which are drawn together to exert an axial compressive force onto the end rings 23 to expand the implant body 12. Indeed, no portion of the expander 14 is in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Likewise, no portion of the expander 14 in any way extends transversely between and

engaging central portions/mid-portions of the axially-extending ribs 26 to expand the implant body. This is clearly and unambiguously evident from Figures 2, 2B and 24 of Kuslich.

As indicated above, the Office Action sets forth very brief rational in support of the rejection of the pending independent as being obvious in view of Kuslich. Specifically, the grounds for the rejection of the pending independent claims is primarily based on the assertion that the location of the expansion member intermediate opposite end portions of the implant would have been obvious “since it would have been held that mere relocation of parts of an invention involves only routine skill in the art”. (Pgs. 2 and 3; emphasis added). However, the Applicant notes that the Office Action fails to address the recitation in the pending independent claims that the expansion member is “engaged with” the first and second axial walls at a location intermediate the end portions/walls. For the sake of argument, even if the assertion set forth in the Office Action that the location of the expansion member would have been obvious in view of Kuslich is accepted, the Office Action fails to set forth any basis or grounds whatsoever regarding how/why it would have been obvious to modify Kuslich such that the post 40 of the implant expander 14 is “engaged with” the axially-extending ribs 26 “at a location intermediate” the end rings 23, as recited in each of the independent claims. Indeed, as indicated above, no portion of the implant expander is in any way engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Instead, the implant is expanded by compressing the end caps 18, 32 against the end rings 23.

The Applicant notes that “[t]o establish a prima facie case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.” MPEP §2142 (citing In re Vaeck, 20 USPQ.2d 1438 (Fed. Cir. 1991)). Additionally, “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (In re Kahn, 441 F. 3d 977, 988 (Fed. Cir. 2006) cited with approval in KSR Int’ v. Teleflex Inc., 127 S. Ct. 1727 (2006)). In the present case, the Office Action fails to articulate any reasoning and/or any rational underpinning as to why one skilled in the art would modify Kuslich such that the post 40 of the implant expander 14 is

“engaged with” the axially-extending ribs 26 “at a location intermediate” the end rings 23 to arrive at the invention recited in the pending independent claims.

Since the grounds set forth in the Office Action regarding the rejection of the pending independent claims as being obvious over Kuslich are conclusory, and do not address each of the features recited in the independent claims, a prima facie case of obviousness has not been established. Accordingly, withdrawal of the rejection of the pending independent claims as being obvious in view of Kuslich is respectfully requested. Additionally, the Applicant further submits that there would be no motivation for one of ordinary skill in the art to modify the Kuslich device such that the post 40 of the implant expander 14 is engaged with the axially-extending ribs 26 at a location intermediate the end rings 23. Indeed, such a modification would significantly alter the operating principles of the Kuslich device, which relies on compressing the ends of the implant toward one another to expand the implant, and does not in any way rely on engagement of the implant expander 14 with the ribs 26 at an intermediate location between the ends of the implant.

Nevertheless, in order to advance prosecution of the subject application, independent claims 1, 33, 37, 45 and 50 have each been amended to recite the expansion member “extending transversely between and engaging” central portions/mid-portions of the axial walls. As indicated above, such amendment does not raise new issues that would require further consideration and/or searching since engagement of the expansion member with the axial walls at an intermediate location between end portions of the implant was already recited in the previous versions of the independent claims. Once again, Kuslich fails to teach or suggest modifying the implant with the implant expander 14 “engaging central portions” of the axially-extending ribs 26 to expand the implant, as recited in each of the independent claims 1, 33, 37, 45 and 50.

Moreover, engagement of the expansion member with the axial walls at a location intermediate the opposite end portions/walls and engagement of the expansion member with central portions of the axial walls not only serves to expand the implant body, but also provides transverse support to the axial walls at a central location of the implant to resist compression loading onto the implant body by the adjacent vertebrae and to provide structural stability and rigidity to the implant body. Indeed, as set forth in paragraph 56 of the published application,

“positioning of the expansion pin 24 within the center compartment 90c of the inner chamber 40 provides additional support and rigidity to the upper and lower walls 30, 32 of the fusion cage 22 to resist compression loads from the vertebral bodies  $V_U$ ,  $V_L$ , particularly near the central portion 22c of the fusion cage 22 which is otherwise devoid of internal support members.” However, the Kuslich implant fails to provide any type of transverse support to the axially-extending ribs 26 at a central location of the implant body 12, but instead relies solely on the axial compressive force exerted onto the end rings 23 of the implant body to expand the implant body and to resist vertebral loading.

For at least the reasons set forth above, the Applicant submits that independent claims 1, 33, 37, 45 and 50 are patentable over Kuslich, and allowance of the same is respectfully requested. Additionally, dependent claims 2-29, 34-36, 38-44, 46-49 and 51-60 are submitted to be patentable for at least the reasons set forth above in support of the patentability of their respective independent base claims.

## CONCLUSION

The Applicant respectfully requests entry of this response to the final Office Action and consideration and allowance of the present application including pending claims 1-29 and 33-60. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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